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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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[REDACTED] EXAMINER

KAM, CHIH MIN

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1656

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/857,000	CLAIR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 28 August 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2,3,5-8 and 10-13 is/are pending in the application.  
 4a) Of the above claim(s) 2,3 and 5-8 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 10-13 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 04 January 2007 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

1. The Request for Continued Examination (RCE) filed on August 28, 2007 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

### ***Status of the Claims***

2. Claims 2, 3, 5-8 and 10-13 are pending.

Applicants' amendment and Declaration of Cecile Bonnafous filed August 28, 2007 are acknowledged. Applicants' response and Declaration of Cecile Bonnafous have been fully considered. Claims 10-11 have been amended, claims 1, 4 and 9 have been cancelled, and new claims 12-13 have been added. Claims 2-3 and 5-8 are non-elected inventions and are withdrawn from consideration. Therefore, claims 10-13 are examined.

### ***Oath/Declaration***

3. An application data sheet (ADS) filed August 28, 2007 to correct the deficiency in the oath or declaration is acknowledged.

### **Withdrawn Claim Objections**

4. The previous objection to claims 9-11 is withdrawn in view of applicant's amendment to the claim, applicants' cancellation of the claims, and applicants' response at page 11 of the amendment filed August 28, 2007.

### **Withdrawn Claim Rejections - 35 USC § 101**

5. The previous rejection of claims 1 and 4 under 35 U.S.C. 101 is withdrawn in view of applicants' cancellation of the claims, and applicants' response at page 11 of the amendment filed August 25, 2007.

### **Withdrawn Claim Rejections - 35 USC § 112**

6. The previous rejection of claims 1 and 4 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of applicants' cancellation of the claims, and applicants' response at page 12 of the amendment filed August 28, 2007.
7. The previous rejection of claims 9-11 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claims, and applicants' response at pages 12-16 of the amendment as well as Declaration of Cecile Bonnafous and Exhibits A-E and G-P filed August 28, 2007.

In the Declaration of Cecile Bonnafous, paragraph 7 states that rodent models of the central nervous system (CNS) are currently regarded as the animal model most closely resembling human models of the CNS; paragraphs 8-10 state that many animal models demonstrate predictability for efficacy in humans (See Exhibits C-E and G-N); paragraphs 11-13 state that the present application discloses working examples performed on non-human models, that is rodent models (See Exhibits O and P); and paragraphs 14-18 state that the specification-as-filed taken in conjunction with state-of-the-prior art provides sufficient basis to expect one of ordinary skill in the art will be able to drive an active substance across the BBB to the CNS or to treat a CNS disease using the aforementioned conjugate recited in pending amended claims 10 and 11 based upon the success of administering vectorized small molecules in human cells.

8. The previous rejection of claims 1, 4 and 9 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation of the claims, and applicants' response at page 16 of the amendment filed August 28, 2007.

***Maintained Informalities***

The disclosure is objected to because of the following informalities:

9. Applicants have added “SEQ ID NO:” into Tables I, VII, VIII and IX. For example, in Table 1, compound No. 1 being Doxo-SynB1, indicated as (SEQ ID NO:11), thus it appears Doxo-SynB1 is SEQ ID NO:11, which is not correct. The table should clearly indicate SynB1, not Doxo-SynB1, is SEQ ID NO:11. See also Tables VII, VIII and IX. Appropriate correction is required.

***Claim Objections***

10. Claims 10-11 are objected to because the claim recites the term “an active chemical molecules”, which should be indicates as “an active chemical molecule”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 10-13 are indefinite because the claim lacks an essential step in the process. The missing step is an effective amount of the conjugate administered, it is not clear what amount of the conjugated is administered in the claimed methods. Claim 11 is also indefinite because of the use of the term “driving one of the following peptides: SynB1 (SEQ ID NO:11) or SynB1 (SEQ ID NO:11) across the BBB to the CNS”. Since SynB1 or SynB3 has the vectoring activity, it is not clear how the active substance comes across the BBB to the CNS in the claimed method. Claims 12-13 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

*Response to Arguments*

Applicants indicate claim 10 has been amended to recite the conjugate is being administered in an amount sufficient to treat the CNS diseases, and claim 11 has been amended to recite the conjugate is being administered in an amount sufficient to drive the peptide of SynB1 or SynB3 across the BBB to the CNS (pages 16-18 of the response).

Applicants' response has been considered, however, the arguments are not persuasive because while applicants indicate "an effective amount of the conjugate" has been added into the claims, claim 10 or claim 11 does not recite the limitation regarding the amount administered, thus the rejection is maintained.

*Conclusions*

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1656

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

November 6, 2007